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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO	
10/044,801 01/11/2002		Jackie Y. Ying	M00925/70110	4734	
23628 75	90 01/15/2004	EXAMINER			
	NFIELD & SACKS, PO	KOSLOW, CAROL M			
FEDERAL RES	SERVE PLAZA C AVENUE	ART UNIT	PAPER NUMBER		
BOSTON, MA 02210-2211			1755		

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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	·	Application N	10.	Applicant(s)					
•		10/044,801		YING ET AL.					
	Office Action Summary	Examiner		Art Unit					
		C. Melissa Ko		1755					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply									
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).									
1)[	Status 1)⊠ Responsive to communication(s) filed on <u>03 November 2003 and 19 November 2003</u> .								
2a)□	ALVE T	his action is non-							
3)□	and the formal methods proceedings as to the merits is								
Disposit	ion of Claims								
4)🖂	4)⊠ Claim(s) <u>581-586,588-599,601-612,614-620,623-639 and 674-697</u> is/are pending in the application.								
,	4a) Of the above claim(s) is/are with	drawn from consi	deration.						
, –	5)⊠ Claim(s) <u>597-599,601-612,614-620,623-639 and 674-695</u> is/are allowed.								
6)⊠ Claim(s) <u>581-586,588-596,696 and 697</u> is/are rejected.									
7)	Claim(s) is/are objected to.								
8)□	Claim(s) are subject to restriction are	nd/or election reqi	uirement.						
]	tion Papers								
9) The specification is objected to by the Examiner.									
10)⊠ The drawing(s) filed on <u>1/11/02</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.									
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).									
	Replacement drawing sheet(s) including the co	errection is required	If the drawing(s) is o	e Action or form	PTO-152				
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.									
_	under 35 U.S.C. §§ 119 and 120		- 25 U.S.O. \$ 110	(a) (d) or (f)					
<ul> <li>12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) ☐ All b) ☐ Some * c) ☐ None of:</li> <li>1. ☐ Certified copies of the priority documents have been received.</li> <li>2. ☐ Certified copies of the priority documents have been received in Application No</li> <li>3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> <li>13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet.</li> <li>37 CFR 1.78.</li> <li>a) ☐ The translation of the foreign language provisional application has been received.</li> <li>14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.</li> </ul>									
Attachme	ent(s)		_						
1) Not	tice of References Cited (PTO-892) tice of Draftsperson's Patent Drawing Review (PTO-94) ormation Disclosure Statement(s) (PTO-1449) Paper N	48) 5 o(s) 6		ary (PTO-413) Paper I I Patent Application (I					

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3 and 19 November 2003 has been entered.

The original patent, or a statement as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

Applicant is reminded of the continuing obligation under 37 CFR 1.178(b), to timely apprise the Office of any prior or concurrent proceeding in which Patent No. 6,013,591 is or was involved. These proceedings would include interferences, reissues, reexaminations, and litigation.

Applicant is further reminded of the continuing obligation under 37 CFR 1 56, to timely apprise the Office of any information which is material to patentability of the claims under consideration in this reissue application.

These obligations rest with each individual associated with the filing and prosecution of this application for reissue. See also MPEP §§ 1404, 1442.01 and 1442.04.

The amendments to the claims of 3 November 2003 have overcome the art rejections.

Accordingly, they have been withdrawn.

The rejection of claims 597-599, 601-612, 614-620, 623-639 and 674-695 under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based is withdrawn. The limitation added to overcome the rejection of the original article claims 24-32 was that the

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particulates have an average apatite crystal size of less than 100 nm. The article claims in this reissue application teaches the particulates have an average apatite crystal size of less than 250 nm. While this limitation is broader than the original limitation in patented claims 24-32, it is not as broad or broader than the original application claims 24-32. Accordingly, the rejection is withdrawn due to the teachings under Principle C, given in the "Updated Guidance as to Applying the Recapture Rule to reissue Applications" memo of 4 August 2003 that such a broadening is acceptable and not recapture. These guidelines will be incorporated into Chapter 1400 with the next revision of the MPEP.

The reissue oath/declaration filed with this application is defective because it fails to contain the statement required under 37 CFR 1.175(a)(1) as to applicant's belief that the original patent is wholly or partly inoperative or invalid. See 37 CFR 1.175(a)(1) and see MPEP § 1414.

The originally filed reissue oath/declaration it fails to contain the statement required under 37 CFR 1.175(a)(1) as to applicant's belief that the original patent is wholly or partly inoperative or invalid with respect to the shape limitations and aspect ratio ranges in new claims 696 and 697.

Claims 696 and 697 are rejected as being based upon a defective reissue declaration under 35 U.S.C. 251 as set forth above. See 37 CFR 1.175.

The nature of the defect(s) in the declaration is set forth in the discussion above in this Office action.

Claims 696 and 697 do not conform to the requirements of 37 CFR 1.173(b)(2). The entire text of the claims is not underlined.

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Since the reply filed on 11/3/03 appears to be *bona fide*, applicant is given a TIME PERIOD of **ONE** (1) **MONTH** or **THIRTY** (30) **DAYS** from the mailing date of this notice, whichever is longer, within which to submit an amendment in compliance with 37 CFR 1.173(b)(2). EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

Claim 696 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no teaching in the specification as to the claimed aspect ratio. While the 37 CFR 1.132 declaration states the claimed particular apatite inherently has this aspect ratio, for the claim to meet the requirements under 35 U.S.C. 112, first paragraph it also needs to be in the specification. Applicant can insert the claimed inherent aspect ratio into the specification. Since this is a reissue application, the amendment to the specification must be made in the manner set forth in 37 CFR 1.173(b)(1). See MPEP 1453

Claims 581-586, 588-596, 696 and 697 are rejected under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. See *Hester Industries, Inc.* v. *Stein, Inc.*, 142 F.3d 1472, 46 USPQ2d 1641 (Fed. Cir. 1998); *In re Clement,* 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball Corp.* v. *United States*, 729 F.2d 1429, 1436, 221 USPQ 289, 295 (Fed. Cir. 1984). A broadening aspect is present in the reissue which was not present in the application for patent. The record of the application for the patent shows that the broadening

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aspect (in the reissue) relates to subject matter that applicant previously surrendered during the prosecution of the application. Accordingly, the narrow scope of the claims in the patent was not an error within the meaning of 35 U.S.C. 251, and the broader scope surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application.

Applicants added the limitations that the apatite crystals in the particulate are spherical and have an average particle size of less than 100 nm to overcome the art and to obtain the original patent. In the reissue claims, applicants have broadened the average crystal size to less than 150 nm, which is not as broad or broader than the original application claims. Under the teachings of Principle C, given in the "Updated Guidance as to Applying the Recapture Rule to reissue Applications" memo of 4 August 2003 that such a broadening is acceptable and not recapture.

The newly presented claims also do not include the crystal shape limitation or state the crystals have a structure from needle-like to spherical. The claims are broader than the patent claims and since the limitations now being omitted or broadened in the present reissue were originally presented and argued in the original application to make the claims allowable over the prior art rejections made in the original application, the omitted limitations in the newly added claims relate to subject matter previously surrendered by applicant, and impermissible recapture exists. See MPEP 1412.02 and the flowchart given in the "Updated Guidance as to Applying the Recapture Rule to reissue Applications" memo of 4 August 2003.

Attachment B of the response includes applicants' arguments given in the original application. These arguments state the shape amendment was added to overcome Nagai et al (U.S. Patent 4,330,514) which teaches elongated or needle-shaped apatite crystals having an

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aspect ratio of 3:1 to 10:1 and the commercially available "Aldrich" hydroxyapatite crystals, which applicants stated are elongated or needle shaped whiskers. Claims 581-586, 588-596, 696 and 697 include elongated or needle shaped crystals having as aspect ratio of 3-10 and crystals having the conventional hydroxyapatite whisker shape, which were clearly surrendered by applicants, based on their arguments in the original application.

To overcome the rejection, applicants will need to amend claims 581, 696 and 697 so they exclude elongated or needle shaped crystals having as aspect ratio of 3-10 and crystals having the conventional hydroxyapatite whisker shape.

Claims 597-599, 601-612, 614-620, 623-639 and 674-695 are allowable over the cited art of record since articles having the claimed properties are not taught or suggested by the cited art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Koslow whose telephone number is (571) 272-1371. The examiner can normally be reached on Monday-Friday from 8:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Bell, can be reached at (571) 272-1362.

The fax number for all official communications is (703) 872-9306.

cmk January 12, 2004 C. Melissa Koslow Primary Examiner Tech. Center 1700